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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,739	12/30/2004	Antoine LaFont	29644/04002	7985
24024 7590 03/26/2009 CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114				
EXAMINER ANDERSON, GREGORY A				
ART UNIT 3773		PAPER NUMBER		
NOTIFICATION DATE 03/26/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com
dcunin@calfee.com

Office Action Summary

Application No.

10/508,739

Applicant(s)

LAFONT ET AL.

Examiner

GREGORY A. ANDERSON

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,19-23 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,19-23 and 27-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 December 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-10, 19-23, and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killion 6,022,371 in view of Lafont et al 5,957,975 in view of design choice.

Killion discloses a method for preparing an assembly for delivering a stent that is substantially resistant to negative recoil when expanded mechanically to a final predetermined diameter in a lumen of a tube, duct, or vessel of a mammalian subject, the method comprising: heating a polymeric cylindrical device which is at a final predetermined diameter and wall thickness to a temperature sufficiently above the glass

transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the device, wherein the final predetermined diameter and wall thickness are substantially the same as the diameter and wall thickness of a stent that has been expanded to a final desired diameter at a target site in a tube, duct, or vessel of the mammalian subject, wherein the device is mounted on a solid support for maintaining the cylindrical device at the final predetermined diameter (Col. 3 ll. 39-45), and wherein the polymeric device has a wall defining a first open end, a second open end, and a channel connecting the first and second open ends (Figs. 3a-3d), rapidly cooling the polymeric cylindrical device at a temperature below the T_g of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter (Col. 3 ll. 45-49); forming slits, voids, or open spaces in the wall of the polymeric cylindrical device (Col. 3 ll. 37-39); and mounting the device on an inflatable balloon catheter (Col. 3 ll. 61-63). The stent will inherently exhibit positive recoil when not fully expanded.

However, Killian does not disclose reducing the diameter of the cylindrical device by heating the device to a temp at or above the T_g of the polymer while evenly applying pressure to the exterior surface of the wall of the device; and rapidly cooling the device below the T_g to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically to the final predetermined diameter by inflation of the balloon. Killian further does not disclose the stent being made from PLA.

Lafont et al. discloses reducing the diameter of the cylindrical device by heating the device to a temp at or above the Tg of the polymer while evenly applying pressure to the exterior surface of the wall of the device; and rapidly cooling the device below the Tg to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically to the final predetermined diameter by inflation of the balloon (Col. 8 ll. 20-35). Lafont et al. further discloses the stent being made from PLA which has a Tg of about 60 degrees C.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the methods of Killion with the methods of Lafont et al. in order to aide in keeping the stent in place on the balloon as taught by Lafont et al. (Col. 8 ll. 32-35).

Killion further does not disclose temperature ranges suitable for polymeric stents, due to the Killion disclosure focusing on those ranges of Nitinol.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the temperature ranges used in setting the stent to match the requirements of the particular polymer since it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

4. Applicant's arguments filed 12 December 2008 have been fully considered but they are not persuasive. The methods used in setting a shape memory alloy or a shape memory polymer are virtually identical, the only difference being that the temperatures capable of being withstood by a polymeric stent are significantly lower than those of a metal stent, in most instances. It is, therefore, not novel to adjust the temperatures used in the heat setting process to match those required by the particular material, regardless of the implicit disclosure of the prior art. Applicant proposes a method of preparing a shape memory polymer stent assembly, subsequently claiming all of the steps necessary to ready the stent for use. The Examiner asserts that these steps are not unusual to an application of any shape memory material. Applicant argues that the device of Killion is not rapidly cooled to a temperature below the T_g of the device. Examiner disagrees. Killion discloses cooling the stent, or allowing it to cool. Cooling the stent is indicative of the temperature of the stent being forcibly lowered, whereas allowing it to cool indicates that the temperature is allowed to come down at room temperature, thus allowing the stent to cool at a much slower pace. Since the rapidity of the cooling process is not claimed, Examiner asserts that the step of "cooling the stent" as disclosed by the Killion reference reads on the claimed limitation. Applicant further argues that Killion does not mount the device on a balloon and subsequently there would be no motivation to use such a balloon. The Killion reference does, as noted by Applicant, disclose that a balloon might be used in the instance where it is necessary to further expand the stent. Lafont et al. discloses clearly a stent being mounted on a

balloon, and due to the disclosure of Killion, it would clearly be obvious that in situations where the self expanding properties of the stent are not enough to fully expand the stent to the size needed, mounting the stent on a balloon would be a proper alternative.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY A. ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

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/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773